



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10691]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10691 Data Request and Attestation for PDP Sponsors

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

Type of Information Collection Request: New collection (request for a new OMB control number);

Title of Information Collection: Data Request and Attestation for PDP Sponsors; Use: Section 50354 of the Bipartisan Budget Act of 2018 (BBA) provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provide prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims about its plan enrollees. Section 50354 of the BBA further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (1) optimizing therapeutic outcomes through improved medication use, (2) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions, and (3) for any other purposes determined appropriate by the Secretary. Section 50354 also states that the PDP sponsor may not use the data: (1) to inform coverage determinations

under Part D, (2) to conduct retroactive review of medically accepted conditions, (3) to facilitate enrollment changes to a different PDP or a MA-PD plan offered by the same parent organization, (4) to inform marketing benefits; and (5) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information. This proposed information collection request would allow the PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in 42 CFR 423.153. Form Number: CMS-10691 (OMB control number: 0938-TBD); Frequency: Occasionally; Affected Public: Private sector; Number of Respondents: 63; Total Annual Responses: 68; Total Annual Hours: 1.36. (For policy questions regarding this collection contact Kari Gaare at 410-786-8612.)

1.

Dated: November 27, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

[FR Doc. 2018-26052 Filed: 11/29/2018 8:45 am; Publication Date: 11/30/2018]